#### Procter & Gamble - I.P. Division

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Number of Pages Including This Page: 11

Inventor(s): Hayek et al.

1) Appeal Brief - 6 pgs..

S.N. 09/845,941 Filed: April 30, 2001

2) Extension of Time - 5 mos. - orig. w/copy

Case: P126

3) Fee Transmittal - orig. w/copy

Comments:

IV. 513 622 3300 P.02/11
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE: +

Complete if Known		
Application Number	09/845,941	
Confirmation Number	3312	
Filing Date	April 30, 2001	
First Named Inventor	Hayek et al.	
Examiner Name	Mojdeh Bahar	
Art Unit	1617	
Attorney Docket No.	P126	
	Application Number Confirmation Number Filing Date First Named Inventor Examiner Name Art Unit	

METHOD OF PAYMENT	FEE CALCULATION (continued)					
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Deposit Account Name: The Procter & Gamble Company	Extension for reply within 4th month (\$1,59)					
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SUBMITTED BY			Comple	Complete (if applicable)	
Name (Print/Type)	Cynthia L. Clay	Registration No. (Attorney/Agent)	54,930	Telephone	(513) 622-0291
Signature	Whia &	_ C) a		Date	2/14/05

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Claims in excess of 20 (\$50 per claim)		
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	Name (Print/Type)	Cynthia L. Clay	Registration No. 54,930 (Attorney/Agent)	Telephone	(513) 622-0291
-	Signature	Callin J.	COG	Date	2/14/05

This collection of information is received by TCFR 1.13. The information is required to actual or reside a breaching by the public which is to the case by the USFTCO to pursual) as applications. Constituting part of information is required to 12 U.S.C. 12.2 and 17 CFR 1.14. This collection is compared to that 12 Dispitation is completed in the contract by 12 U.S.C. 12.2 and 17 CFR 1.14. This collection is compared to that 12 Dispitation is completed in the contract by the public which is to the USFTCO TINN will very operating upon the birth-layer contract in the compared for the contract in the compared to the USFTCO TINN will very operating upon the birth-layer contract in the compared for the contract of the property of the public which is to the USFTCO TINN will very operating upon the USFTCO TINN will very operation for including pathways and the contract of the public which is to the USFTCO TINN will very operation of the USFTCO TINN w

# RECEIVED CENTRAL FAX CENTER

FEB 1 4 2005

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

09/845,941

Applicant(s)

Hayek et al.

Filed

April 30, 2001

Title

Pet Food Composition For Reducing

Inflammatory Response In Cats

TC/A.U.

1617

Examiner

Mojdeh Bahar

Conf. No.

3312 P126

Docket No.

27752

#### APPEAL BRIEF

Mail Stop Appeal Brief - Patents Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450 Dear Sir.

This Brief is filed pursuant to the appeal from the U.S. Patent and Trademark Office decision mailed June 16, 2004 finally rejecting Claims 1-4, 10, and 11. A Notice of Appeal was timely filed on September 24, 2004. Attached hereto is a Petition for Extension of Time, and the fee required under 37 C.F.R. § 1.17(a)(1), providing for a timely filing of this brief to and including February 24, 2005.

#### REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

## RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

#### STATUS OF CLAIMS

Claims 1-4, 10, and 11 are finally rejected. Claims 6-9 are withdrawn.

Claims 1-4, 10, and 11 are appealed.

A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

### STATUS OF AMENDMENTS

No amendment was filed.

# SUMMARY OF CLAIMED SUBJECT MATTER

The present invention claims a pet food composition comprising an effective inflammatory response-reducing amount, on a dry matter basis, of omega-6 and omega-3 fatty acids in a weight ratio of about 5:1, the omega-3 fatty acids comprises at least about 80% alpha-linoleic acid derived from flaxsced oil, by weight of the omega-3 fatty acids, and the majority of omega-6 fatty acids are derived from flaxsced oil, the composition comprising from about 7 to about 14% by weight total fat, the composition is formulated as a cat food. (specification page 3, lines 28-35 and page 4, lines 1-13).

# GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- (I) Rejection under 35 U.S.C. 103(a) over EP Patent No. 0678247.
- (II) Rejection under 35 U.S.C. 103(a) over EP Patent No. 0678247 in view of U.S. Patent No. 4,229,485.

#### **ARGUMENTS**

Claims 1-4 are patentable over Reinhart because the reference fails to teach or suggest all of the claimed limitation of the present invention.

The Examiner has rejected Claims 1-4 under 35 U.S.C. § 103 in view of Reinhart. The Examiner states that Reinhart teaches pet foods containing omega-6 and omega-3 fatty acids, at a ratio of from 3:1 to 10:1. The Examiner further states that the source of these fatty acids may be from a variety of sources, including fish oil and flax.

The Examiner states that Reinhart teaches that the percentage of crude fat is 20% to 23%, but does not teach crude fat in the range of from about 7% to about 14%.

Reinhart discloses that Menhaden (fish) oil is a concentrated source of eicosapentaenoic acid; that flax oil is a concentrated source of alpha-linolenic acid; and that safflower oil is a concentrated source of linoleic acid. Reinhart states that each of these sources can be utilized to prepare compositions having omega-6 to omega-3 fatty acid ratios of 5:1; 10:1; 25:1; 50:1; or 100:1. In the present invention, Claims 1 – 4 require pet foods comprising omega-6 and omega-3 fatty acids, wherein the ratio of these components is about 5:1. Moreover, Appellants' claims require the majority of the omega-6 fatty acids to be derived from flaxseed oil and at least about 80% of alpha-linoleic acid derived from flaxseed oil, by weight of the omega-3 fatty acids.

In contrast, Reinhart fails to teach or suggest any difference among sunflower, fish or flaxseed oil, or any preference among fish or flaxseed oil, or any other source of omega-6 or omega-3 fatty acids, at any total fat level in any composition. Moreover, Reinhart fails to teach or suggest use of flaxseed oil specifically, to provide highly concentrated levels of omega-3 and omega-6 fatty acids. Indeed, as Appellants' claims omega-6 fatty acids, the majority of which are derived from flaxseed oil, and omega-3 fatty acids, in which at least 80% is linoleic acid derived from flaxseed oil, Reinhart fails to make any suggestion of such specifications. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The criticality of these claimed elements has been demonstrated and disclosed in the present specification. Appellants' have explicitly shown that at the low levels of fat recited in Appellants' claims (which are not suggested by Reinhart), there is a critical source of omega-3 fatty acids and omega-6 fatty acids which should be used. Indeed, Appellants' specification states that "whereas both fish oil and flaxseed oil can be included in the feline diet to reduce inflammatory response, flaxseed oil offers a better alternative in a lower lipid (14%) diet because flaxseed oil shows minimal immunosuppressive activity compared to fish oil." See Appellants' specification, page 12.

The Examiner requested an understanding of the practical effect of the present discovery. As is commonly understood immunosuppressive activity is linked to inflammation, and omega-3-fatty acids have also been shown to suppress immune function, particularly in immunosuppressed individuals. See e.g., Wu and Meydani, "n-3 Polyunsaturated Fatty Acids and Immune Function, Proc. Nutr. Soc., Vol 57(4), pp. 503 – 509 (1998); Meydani, "Effect of (n-3) Polyunsaturated Fatty Acids on Cytokine Production and Their Biologic Function," Nutrition, Vol. 12 (1 Suppl.), pp. S8 – 14 (Jan. 1996); Meydani and Dinarello, "Influence of Dietary Fatty Acids on Cytokine Production and its Clinical Implications," Nutr. Clin. Pract., Vol. 8(2), pp. 65 – 72 (Apr. 1993) (abstract copies attached for the convenience of the Examiner). As such, that flaxseed oil has been shown by the inventors to contribute to minimized immunosuppressive activity is indeed exciting and presents practical ramifications of enhanced use of omega-3-fatty acids in the pet food compositions of the present invention.

Since unexpected results have been shown at this level of lipid (i.e., a break-out amongst sources of omega-3 and omega-6 fatty acid), non-obviousness of Claims 1 – 4, has been demonstrated. Reinhart fails to teach or even suggest low levels of dietary fat (from about 7% to about 14%) in combinations with the criticality of omega-3 or omega-6 fatty acid source at this specific level.

Therefore, Appellants contend that the claimed invention is unobvious and that the rejection should be withdrawn.

Claims 11 and 12 are patentable over Reinhart in view of Brown because the reference fails to teach or suggest all of the claimed limitation of the present invention.

The Examiner has rejected Claims 10 and 11 under 35 U.S.C. § 103 over Reinhart in view of Brown. The Examiner states that Reinhart teaches pet foods containing omega-6 and omega-3 fatty acids, at a ratio of from 3:1 to 10:1. The Examiner further states that the source of these fatty acids may be from a variety of sources, including fish oil and flax. The Examiner states that Reinhart teaches that the percentage of crude fat is 20% to 23%, but does not teach crude fat in the range of from about 7% to about 14%.

The Examiner further states that Brown teaches that cat foods can be in canned or kibble form.

Appellants assert that the arguments presented above regarding Reinhart in traversing the § 103(a) rejection also apply to the present rejection. The Reinhart reference fails to teach or even suggest low levels of dietary fat (from about 7% to about 14%) in combinations with the criticality of omega-3 or omega-6 fatty acid source at this specific level.

Moreover, as Brown does nothing to remedy the deficiencies of Reinhart, the nonobviousness of Claims 10 and 11 has also been demonstrated. That Brown teaches canned and kibble cat foods is immaterial to the inventive discoveries relevant to low levels of lipid in combination with the specified omega-3-fatty acid, flax seed oil. The combination of Reinhart and Brown does not teach or suggest each and every element of Appellants' presently claimed invention.

Therefore, Appellants contend that the claimed invention is unobvious and that the rejection should be withdrawn.

#### SUMMARY

In view of all of the above, it is respectfully submitted that the aforementioned rejections are erroneous. The Board's reversal of the rejections is respectfully requested.

Respectfully Submitted,

THE PROCTER & GAMBLE COMPANY

Cynthia L. Clay

Registration No. 54,930

(513) 622-0291

February 14, 2005

Customer No. 27752

### CLAIMS APPENDIX

- 1. (Previously amended) A pet food composition comprising an effective inflammatory response-reducing amount, on a dry matter basis, of omega-6 and omega-3 fatty acids in a weight ratio of about 5:1, wherein the omega-3 fatty acids comprises at least about 80% alpha-linoleic acid derived from flaxseed oil, by weight of the omega-3 fatty acids, and wherein the majority of omega-6 fatty acids are derived from flaxseed oil, said composition comprising from about 7 to about 14% by weight total fat, which composition is formulated as a cat food.
- (Original) The pet food composition of claim 1 in which at least about 20 wt% of the total fatty acids are omega-6 fatty acids.
- 3. (Original) The pet food composition of claim 1 in which at least about 4 wt% of the total fatty acids are omega-3 fatty acids.
- (Original) The pet food composition of claim 1 in which said omega-3 fatty acids further comprise eicosapentaenoic acid, docosahexaenoic acid, or combinations thereof.
- (Canceled).
- 6.-9. (Withdrawn).
- 10. (Previously amended) The pet food composition of claim 1 which is a solid cat food selected from the group consisting of dry kibble, moist chunk foods, moist canned cat food and cat treats.
- 11. (Previously amended) The pet food composition of claim 10 which is fortified with vitamins and micronutrients.